TRANSCRIPT OF PROCEEDINGS

DEPUTY ADMINISTRATOR STAKEHOLDER)
MEETING WITH BILL FREESE,)
FRIENDS OF THE EARTH)

Pages: 1 through 40

Place: Riverdale, Maryland

Date: September 22, 2005

HERITAGE REPORTING CORPORATION
Official Reporters
1220 L Street, N.W., Suite 600
Washington, D.C. 20005-4018
(202) 628-4888
hrc@concentric.net

UNITED STATES DEPARTMENT OF AGRICULTURE

DEPUTY ADMINISTRATOR STAKEHOLDER)
MEETING WITH BILL FREESE,)
FRIENDS OF THE EARTH)

Room 2A06
Department of Agriculture
4700 River Road
Riverdale, Maryland

Thursday,
September 22, 2005

The meeting was convened, pursuant to notice, at 2:10 p.m.

PARTICIPANTS:

FOR THE USDA:

CINDY SMITH
Deputy Administrator
USDA - APHIS - BRS
4700 River Road
Riverdale, Maryland
(301) 734-7324

CLINT NESBITT
AAAS Fellow, Office of Science

JOHN TURNER
Director, Policy Coordination Division

NEIL HOFFMAN
Director, Environmental Risk Analysis Division

MICHAEL WACH
Policy Analyst

APPEARANCES CONT'D

CRAIG ROSELAND
Biotechnologist

SALLY McCAMMON
Science Advisor

ANDREW ROBERTS
AAAS Fellow, Office of Science

DAVE HERON,
Assistant Director, Policy Coordination Division

MIKE BLANCHETTE
Environmental Protection

REBECCA STANKIEWICZ GABEL
Regulatory Analyst

FOR FRIENDS OF THE EARTH:

BILL FREESE
Friends of the Earth
1717 Massachusetts Avenue, NW
Suite 600
Washington, D.C. 20036
(301) 985-3011

P R O C E E D I N G S

(2:10 p.m.)

MS. SMITH: Welcome, Bill. We're glad you came in. You are the first stakeholder to take us up on our offer to hear any thoughts that stakeholders have about our regs, and I'm just here to welcome you and tell you we really appreciate you coming. Then I'm going to turn it over here to Clint, who's actually going to moderate the session for us.

MR. NESBIT: I'd just like to begin by giving a few comments about the nature of our meeting today. It is the intent of these meeting days to provide stakeholders with an opportunity to come in and provide us comments on the record. We are primarily focusing the stakeholder meetings on the issues that are related to our programmatic EIS and our future rule revisions.

We are, as you know, creating an official transcript of this meeting and it will be posted on the web site, made publicly available, as will a list of the names of everyone here in the room today.

We also have to acknowledge that because we are currently in litigation with your group we are somewhat limited in our ability to speak in this kind

of informal setting without our attorneys present. So formally, this is, the ball is in your court to do most of the talking. Despite the fact that that makes things a bit awkward, we do feel that it's very important to give you the opportunity to give us your input for our process and the things that we're considering. And I just want to reiterate to you that we're here to listen to your input and hope that we have a very productive listening session.

MS. SMITH: Bill, would you like us to tell you everyone that's here? There are some new faces that you're not familiar with.

MR. FREESE: Sure. Yeah, I think a few.

MS. SMITH: I'll start. Cindy Smith, Deputy Administrator.

MR. TURNER: John Turner, Director of Policy Coordination Division.

MR. HOFFMAN: Neil Hoffman, Director of the Environmental Risk Analysis Division.

MR. WACH: Mike Wach, Policy Analyst.

MR. ROSELAND: Craig Roseland, Biotechnologist.

MS. McCAMMON: Sally McCammon.

MR. ROBERTS: Hi. I'm Andrew Roberts, and I'm a AAAS Fellow in the Office of Science.

MR. HERON: I'm Dave Heron, I'm the Assistant Director of the Policy Coordination Division.

MR. BLANCHETTE: Mike Blanchette, Environmental Protection.

MR. NESBITT: I'm Clint Nesbitt. I'm a AAAS Fellow in the Office of Science here.

MS. STANKIEWICZ GABEL: I'm Rebecca Stankiewicz Gabel, I'm a regulatory analyst.

MR. NESBITT: So if you would, Bill, we'll allow you to introduce yourself and the floor is yours.

MR. FREESE: Sure. I'm Bill Freese. I've been a research analyst with Friends of the Earth since I guess 1999, and have been working mostly on transgenic crops and their regulatory and scientific aspects.

I know many of you already, have submitted comments on various proposals that you've put out there including the programmatic EIS. I guess it was what, January 2004.

I guess I should say this might be a somewhat short session because I'd kind of forgotten about the litigation rules. I wasn't sure if that was still going to apply because I actually had a lot of questions. I thought it was going to be a little more two-sided. I guess I can still put those questions

out there.

I'm trying to remember how we were going to deal with that before. Didn't you say that you might get back to me in writing or something?

MS. SMITH: I know we had put some information together at the time on some of the key points. I think we talked with you a little bit about some of the key points, but what we could do is why don't we have you put the questions out there, we'll track what they are, and we've got a reporter, and then do the best we can to try to follow up. If there are some things we can talk about today, we will. And my sense is anything that we talk about openly where a group asks us to come in and we say here's what our thinking is, we can share that much I think comfortably. I think it's probably more an issue of not braving new territory that we haven't shared elsewhere that our lawyers would probably want us to kind of run by them first.

Why don't you let us know what your questions are, we'll track them through the meeting, we'll see what we can respond to, and then for the remainder we'll have Clint follow up with you and see what we can give you after the session.

MR. FREESE: Okay, and just to clarify, wouldn't this issue, wouldn't it just apply to the programmatic EIS?

MS. SMITH: Which issue?

MR. FREESE: The issue of not being able to answer me without clearing it with your lawyers.

MS. SMITH: And the programmatic EIS is what we're here to talk about. The programmatic EIS, what our thinking is in that, and then of course that's preparation for the new reg. So those are the two things that we really hope to be talking about with stakeholders when they come in. And of course any topics relevant to that. I understand you were --

MR. FREESE: That's what I was thinking, maybe raise a few related issues.

MS. SMITH: Yeah.

MR. FREESE: Okay.

I guess I won't repeat. When I came in here before I think I kind of summarized the comments I'd submitted for Friends of the Earth back in April of 2004, so I won't repeat that.

Is there any sort of brief update that you folks could share with me on the progress of EIS? Like

maybe timeline? Or is that --

MS. SMITH: We're happy to talk about it. We don't have very concrete information. What we are hoping at this point is to have something out by the early spring in terms of a draft EIS. We are probably within some few number of months of having something ready to start into the clearance process and then we expect the clearance process to -- There's an intra-departmental and inter-agency clearance process that the document will be in for some time, so we're hoping to actually publish the draft EIS in the early spring. We've already started work on the reg. We had a workshop here where we kind of closed BRS down to any other business for two days and we all focused on some of the more operational issues in the reg.

Some of those were things that as we've been working with the reg over the last number of years a number of the staff have said you know, while we're revising things we really should take a look at this, and we can probably do this procedure a little better, or clarify that. So we had a meeting on those issues which were much more smaller picture operational issues than what you're looking at in the EIS which is the bigger issues.

So we have done some initial work to kind of lay the foundation for us to be ready to move on the draft under the proposed rule we hope within some few months after we issue the draft EIS.

MR. FREESE: Okay.

MS. SMITH: Of course all of that's dependent upon workload and resources.

MR. FREESE: Sure.

MS. SMITH: It's a high priority for us, but it is a very big, complicated project that we want to make sure that we give full attention to.

MR. FREESE: It's interesting. There's a really broad range of issues addressed in it. I was surprised that it all got put into one scoping proposal.

I guess maybe I can just briefly reiterate, one of the biggest concerns that we had with EIS was the adventitious presence, the proposed policy or kind of the suggestions on how that might be implemented. And I guess we're, you know, we're very concerned --

I guess I could say that one thing I've noticed, looking at the field trial database there seems to be a trend towards perhaps fewer permits being issued. At least maybe 2003, 2004, but larger permitted

acreage per permit. And that suggests that maybe field trial size is getting bigger. Perhaps I'm wrong there, but that's kind of something I've noticed.

I guess with adventitious presence it seems like that kind of relates to the whole issue of the potential for amplification of traits from adventitious presence.

That's a real concern that I haven't really seen talked about too much. The assumption seems to be that if a trait gets out there at low and intermittent levels, which of course is left very undefined, that it will just not be at all of a problem. And yet it seems like there really is this potential, at least in certain circumstances, certain traits, certain crops, for an amplification of traits that are released into the environment.

MS. SMITH: I think we could share with you a little bit about what we're thinking about for AP. Would you like us to start with that?

MR. FREESE: Sure.

MS. SMITH: That might help tailor your comments.

Do you want to talk a little bit about that?

MR. TURNER: Yeah, I wonder if I should have the mike closer.

MS. SMITH: I think you should.

MR. TURNER: When we think about AP and our new regulations, it's really linked very closely to something else in the NOI which is this tiered permitting system. As you know right now, if someone wants to do a release they would get a notification or a permit and permits vary widely and the types of conditions that may apply. We have some flexibility there from pharm permits to other types.

Under our new system we're thinking more of maybe not having anything called notification, but having a permit, maybe a Type A, Type B, Type C. Those are just examples. We're not 100 percent sure on the number of tiers. Which would correspond to different confinement strategies based on what it was.

So the way that AP might fit into this is that one of the permit tiers which would correspond to things you're very familiar with, and say the Type A which might be somewhat similar to notification now, would be the one for which there would be allowable AP, assuming they met the criteria at the other agencies.

So there are safety criteria for AP that are an integral part of the permit tier. So there's not AP

of anything as you know in 2002 when the U.S. government did our AP policy, that didn't apply to pharmaceuticals and industrials. So at least that notice didn't apply to those. But we would be thinking more in terms of more familiar traits under a more relaxed confinement strategy that met certain safety criteria. So that's AP.

So we're exploring whether we could consider the status of food safety review either at FDA or EPA, whether that's possible under our authority. We're not sure on that yet but that's a possibility.

MR. FREESE: But you would have your own separate environmental --

MR. TURNER: Yeah, ours would be principally environmental so we would have environmental safety criteria that would fit them into the various tiers. There might only be one tier then for which there would be allowable AP.

MS. SMITH: And one thing to keep in mind is with the new definition that we're considering in the Plant Protection Act, we're considering whether to leverage the noxious weed authority, for example, as a way to broaden the scope of our authority.

The definition of a regulated article, what we're

regulating, could be broadened significantly that we could look beyond just environmental criteria. That clearly is our focus, but that definition refers to something that's a noxious weed as something that can affect human health, irrigation, navigation, agriculture, a wide range of issues. So that's a way that we feel -- That gives us what we need to explore whether those criteria that we're looking at we could look beyond just the environmental criteria, for example, it would have to be something that's safe for food.

MR. FREESE: And if you did expand your purview to noxious weed risk do you foresee that being included in your permit A review, or just maybe the higher levels or --

MR. TURNER: I think so. It would be plant pest criteria plus other new criteria based on the noxious weed authority, if we do it.

MR. FREESE: Would it cover something like agricultural, herbicide tolerant weeds seem to be an issue that's been arising. Which is linked to high use of -- herbicide tolerant crops.

MR. TURNER: It seems that there's a broad number of things we could possibly consider, but that

specifically I wouldn't be able to answer exactly what we would look at with respect to herbicide tolerance. But we are looking to broaden the scope of what would be regulated and the parameters which we would consider.

MS. SMITH: Do you have some suggestions along those lines? If you were in the position of identifying what those criteria are, in order to meet essentially the least confinement strategy, the tier of a multi-tier system, do you have thoughts on what kind of a criteria we should be considering or --

MR. FREESE: I have to say, I don't think -- Friends of the Earth doesn't think that the notification category is nearly, that you take nearly enough care in looking at what's going on, the permits before the plant's release into the environment. So if this Category A is similar to the notification I can't say that we could really support it.

MS. SMITH: Do you have some thoughts on specifically what you'd like to see different there? Or are there some areas you think are things you'd like to see us strengthen?

MR. FREESE: Well, it sounds like if you do this ABC system, and notifications account for what, in the

high 90 percent of your permit, so it's basically everything except the non-food. Maybe that's a question that, the permitting system as it's currently set up, is it just for non-food products or do you have a more expansive definition? It's phyto-remediation, I guess.

MR. HOFFMAN: There are also permits for turf grasses and for genomics projects, for example, where they have a lot of genes, there's not as much familiarity with some of those --

MR. FREESE: Like knockout kind of experiments.

MR. HOFFMAN: If they have a knockout and essentially there may be hundreds of knockouts, not always knowing what the functions of those genes are.

MR. TURNER: If it were considered a weed in the area of introduction there should be a plant that wouldn't qualify under notification.

MR. HOFFMAN: And we'll be reexamining that, whether everything under notification should be there or should some things fit in a more stringent tier.

MR. FREESE: But this AP policy wouldn't apply to the other two categories? Is that kind of your present thinking?

MS. SMITH: You look at AP differently based on

the tier, so one tier you would say that there is no recognition that a low and intermittent level of one tier, you wouldn't treat it the same was as you might for this least confinement tier. So essentially you're saying it's kind of, there would be some where it would be non-applicable, but you'd look at what's in that tier to determine what the relationship for AP should be, what those are. That didn't come out as clear as I'd hoped.

MR. TURNER: AP also, any AP question is fundamentally an interagency question. So in 2002 we paved the way forward for things other than the pharmaceuticals. There may in the future be some policy toward those, that relies on food safety assessment and things the other agencies would do.

MR. FREESE: I think for example Bt. There's always the risk that's been most often raised is the allergenic risk of proteins stable to digestion, so you could on the one hand call it a familiar trait and you might think it would fall under the A system but then you've got this -- I realize that would be an EPA concern, I guess, for them to deal with.

I guess my broader point is with the familiar traits you could --

MR. TURNER: And they're moving forward also. We can't speak for them.

MR. FREESE: Is there a problem with like the interagency coordination? A trait that would be familiar to you based on your criteria, your purview, might not be, might require a more thorough review from another agency's criteria. I guess I'm not quite clear on how that would work out.

MR. TURNER: We're not the single gate-keeper for the other agencies so if it didn't have its early safety assessment or its tolerance then it would be illegal for food.

MR. FREESE: Still, for the field trial stage the other agencies don't have to do anything so if there's AP that occurs in the field trial stage it seems like --

MR. TURNER: We're moving forward with a way to address those issues very early in the field testing.

MR. FREESE: One thing, I don't know if this is directly related to the EIS, if you can help me here, but I think it probably relates. I think it would be valuable for the public to know what are the criteria for deciding whether or not to do an environmental assessment of some sort of a field trial. I believe

I've gotten a sense that you have some kind of scoring system. I have seen your work sheets here, I forget what you call them exactly, but where you have the various size of the field trial and other kind of criteria, but it's not evident from that worksheet how the scoring works.

It seems like that would be a valuable thing for the public to have and it's not sensitive or anything, just kind of clarify your thinking about how you decide whether a field trial merits an environmental assessment versus just a simple worksheet.

MS. SMITH: I think that's something we can take under consideration. Given the lawsuit, the points in the lawsuit, that's probably as much as we can do, but point taken.

MR. FREESE: Okay.

I guess I had another question related to the adventitious presence. I hope it isn't going too far afield, but it strikes me, it's kind of interesting that just as you're working to formulate this policy or your part of this broader interagency policy that we had the Bt10 episode. It didn't occur to me right away, but it struck me at a certain point that this is just the sort of thing that an AP policy is meant to

apply to. I mean I would think. I was just -- I guess I was wondering -- I guess I know you fined Syngenta for letting this unapproved or non-deregulated variety get out into the seed supply, but I'm wondering how your response might have differed had this policy, AP policy that you're considering, had it been in place. Do you see what I mean?

MS. SMITH: It's hard to, since the policy's not in place it's kind of hard to anticipate that, but I think the -- Certainly the situation here is that this was something that was not approved to move, and so every time that it did, that required a violation or resulted in a violation of our regulations. That's where we ended up in terms of doing a full investigation -- Every time it moved when it shouldn't have or without the appropriate --

MR. FREESE: Moved meaning like sale, for instance, or transfer?

MS. SMITH: Our authority -- When I say moved, in terms of our authority, it's moved interstate, from one state to another, imported into the country, or released into the environment which means being brought in the field. So each of those movements are what our investigation identified. Then of course

their fine is based on a number of factors including how many counts of those violations.

I don't think we'd be in a position to really conjecture how that might have been different with an AP policy in place since we've not finalized what it is yet.

MR. TURNER: Speaking not specifically to Bt10, but a policy in place that would lay out how these things would be handled so that the status would be known, there would be less case by case evaluation by the government.

MR. FREESE: So at least it would give you a more set framework for dealing with incidents like this? Okay.

As you probably know, we were kind of concerned, we weren't convinced that this was handled in the best way.

As it stands now, will Bt10, I guess it won't be deregulated, or there hasn't been an application --

MS. SMITH: They have not submitted a petition to us to deregulate it.

MR. FREESE: Because I think that's happened, I think something like that has happened in the past, maybe with canola, that, a transformation event that

wasn't intended, that wasn't intended for commercial release got mixed into a variety that was deregulated and the applicant or the decision was made to go ahead and get deregulation for the mistakenly released --

MS. SMITH: As you express some dissatisfaction in how we handled that situation, is there anything you've been thinking that we should be doing differently as we revise our regs? Something that that issue might have raised.

MR. FREESE: Well, I guess there's parts of it -- Just the fact that it took so long for the information to come out. I know that's not your responsibility but that was obviously a concern to us. I think it took months and months for the information to finally come out. That might be more at the EPA's doorstep, I'm not clear on the details of that.

In terms of the regulations I can't think at present.

MS. SMITH: Okay.

MR. FREESE: I noticed that one of the points was to maintain some sort of regulatory authority over a crop after it was allowed for commercialization so that it wouldn't be an absolute deregulation, but more of a conditional one at least in certain cases. We

actually think that's a good idea, that there does need to be some control after the deregulation. I'm wondering if you've progressed in your thinking on that or if there's anything you can say about that.

MS. SMITH: What we're talking about there is we're exploring whether there might be situations in which we are by and large satisfied with the safety of a crop or something that's put before us to be deregulated. So let's say it's 98 percent safe, but there's some scientific issue associated with that that we think there would be benefit to -- This is an example. Benefit to allow that to move forward, but in conjunction with some question that you're going to try to gather data to answer, and then have some, let's say it's a conditional approval. This is all being explored, so none of this is worked out. Conditional approval for three years to gather data to answer this one question that doesn't put a big safety issue on our mind, but something we think we'd like to have some more information on.

That would give us kind of an end point then to come back and look at that question and see if enough information was gathered at that point to resolve that slight issue that was still in our mind. So that is -

-

MR. FREESE: A minor unresolved risk?

MS. SMITH: Yes, a minor, yeah. So that's kind of what we're thinking about. I'd be interested in if you have some thoughts on that, and particularly any examples of something that you might imagine would come before the regulatory system where it would be valuable for us to have that ability to do that.

Of course that being said, that's separate to what we have now which is anything that's deregulated, if some new scientific information becomes available or some new information becomes available we can pull it back in. We already have the ability to do that. But this is more letting it move on into the commercial system with some kind of a question that we want to gather some more data about.

So I don't know if you had any --

MR. FREESE: It just strikes me that that's a little similar to EPA's kind of, they have a periodic registration or re-registration of the Bt pesticides and crops, and that does make sense to be able to -- That would be a little broader approach, the EPA's, to do a thorough reassessment or supposedly do a thorough reassessment, to decide whether they should be re-

registered.

I had kind of thought you were thinking, and I'd actually like to recommend kind of a conditional approval more along the lines of-- I can see cases where you might want to restrict, have deregulation but under restricted conditions. For instance, you've got so many herbicide tolerant weeds here, this could aggravate an existing problem, or something along those lines where it's not --

MS. SMITH: I appreciate your point, and that is one of the other things we had talked about before as well. So that is something that is under consideration. I do welcome your comments along those lines.

MR. FREESE: Just as an example, I've noticed that there are at least, well one variety of herbicide tolerant rice has been deregulated and I think two others are still, the last I checked are still in field testing. Obviously there you have the potential for, well rice doesn't cross-pollinate so much but I could still see a potential for having kind of like a canola situation where you have multiple resistance. Red rice with multiple herbicide tolerance, which could be an issue. You don't want to go back to 2, 4-

D or something like that.

I guess on the pharmaceutical crop front, is there anything you could brief me on in that area? In that arena?

MS. SMITH: Generally there are two things that I think you see in the notice there. One is having a new mechanism to look at how -- a new way to grow pharmaceutical crops while there's full government oversight. And our thinking there is the pharmaceutical crops and industrial crops are something that probably requires a little different thinking in how you approach them that some of our traditional food and feed crops -- there's a lot more public interest, so how can we provide oversight for those in a way that's more transparent?

There's a lot of interest at the state level from our state partners about permits being issued in their state, so how can we create an opportunity for the state to have a greater role in terms of that work?

MR. FREESE: Can I interrupt you just --

MS. SMITH: Yes.

MR. FREESE: I've never become completely clear on the situation at present. Just kind of the division of authority. I mean I guess the way I

understand it is that APHIS has ultimate authority on field trials in states but that you pay a lot of attention to what the state says, but I'm just, I guess I'm not clear on whether the state has kind of formal authority on allowing or rejecting a field trial.

MS. SMITH: Our current regulations as they're written state that we will inform the states. So we'll provide them information. Then we take that a step further and allow states an opportunity to review the information about a field test and then to concur with the permit.

Different states handle that in different ways. Some states would like more time, some don't need as much time, so we provide them information and then they respond back to us. We've never had a situation in which a state has said we won't allow this field test to go on in our state.

We give them the opportunity to raise any concerns that might be relevant to their local area. We appreciate that the state probably has prospective and information that's relevant in terms of a very specific local situation or a cultural situation, so they're given the opportunity to raise those, and then

we work with them to potentially add additional permit conditions or provide them additional information. At times they'll identify permit conditions and then they actually become our permit conditions onto the permit that we issue.

So that's kind of how we do it, that's pretty much how we do it now. --

MR. FREESE: Can I just ask one quick question before I forget? You said that your regulations are just written, that you inform the states but that you have kind of developed a policy --

MS. SMITH: And in addition to that obligation we have had in place a system in which we look to the state to concur with that permit. But we're not required to do that.

MR. FREESE: That's informal. Okay.

I'm sorry.

MS. SMITH: That's okay. and what we are doing, we do have several state initiatives where we're asking the states to look at their role and make any recommendations about what that interface should look like between us and then.

MR. FREESE: And taking a more active role, you're saying?

MS. SMITH: If that's what they want to do. We're saying look at how we interact now, specifically for example that process where we send you the package of information and we say we'd like your concurrence in 30 days. Look at how that interaction goes and is there something about how you'd like that to be handled differently. So we'll be having a further dialogue with the states in the next few months about opportunities to review the regs, to address their issues.

MR. FREESE: Revise regs or just kind of change the informal procedure?

MS. SMITH: It could be both. Some changes we might want to make would require a rule change and others would be just changing the procedure. For example, we've recently automated sending our permits. We now send the permits to the states electronically instead of the paper version. So one of the, a couple of the ag commissioners told me one day, you e-mail that to me I don't have time to read my e-mail, can you send it to my secretary too? So we went back to the states and said okay, who all do you want us to send these to? We don't need to make a reg change to do that. But if there's something more significant

then that might require a reg change to be actually in the reg.

MR. FREESE: One thing for a possible reg change, and let me make sure I've got this right, but as I understand it in certain cases you pass on only the CBI deleted version of the application to the state. If certain states have sunshine laws or whatever. And it seems like -- I realize it's a tough position but it seems like states deserve full information. I would recommend that they should always receive the full application so they know what they're dealing with.

MS. SMITH: I appreciate that. And of course we have to proceed under our legal obligations to protect confidential business information, but we certainly are having a good dialogue with the states about how to address their need for information.

So one example of, we started out talking about what we might want to consider separate for, a different mechanism for growing pharmaceuticals under permit is that increased transparency. One of the things we've kicked around internally is, is there another version, some other document that would be submitted with a permit application for growing a

pharmaceutical that gives as much information as possible without disclosing confidential business information. It would give you a pretty good sense of what you're dealing with so you knew what the issues were, but not betray any confidential business information.

MR. FREESE: So maybe a fuller description of the protein involved rather than just a very short -- That would be an improvement I would think, yeah.

On the whole CBI issue, this is just a general point I've raised before here. I still find, looking at least at the web site that there is either information missing, that it's just not called CBI, the block is blank. And in other cases it is called CBI.

There are examples I've seen where I know what the field trial is for other reasons and yet the information's not there. So I just wonder if you could perhaps revisit your CBI, how do you put it. Be I guess a little more critical before accepting CBI claims from industry. My impression is there are still illegitimately claimed CBI that you're kind of protecting when you really don't need to.

MR. TURNER: In terms of that they've been

disclosed somewhere else.

MR. FREESE: Exactly. Sometimes I've seen it in the media and it's like a field trial of this in the state and it couldn't be anything else. There's only one match for the database.

MS. SMITH: One of our more recent hires in BRS as we build the program more than it's been is the hiring of a documents control manager. That's a position that we had historically that was kind of a gatekeeper on CBI, then that position subsided, so we've reinitiated that position. That's Ingrid Berlanger is the person in that position. Part of her responsibility is to look at developing what we might do systematically to ensure that CBI being claimed really is CBI. Historically we used to do some review, and there's still review that's gone on now. If a biotechnologist is looking at a permit application and they're doing some of their research in terms of addressing it and they see something on the internet that is claimed as CBI, then they call the company and then that change is made.

So we're doing it kind of on a case by case basis now as it comes up, but what we're asking Ingrid to do is put something in place that does it more

systematically. So I'd encourage you if you have any thoughts on that to e-mail her, what she might want to do as well as -- Certainly if you see examples of something that's claimed as CBI or if you see a certain company continues to claim a certain type of information that you continue to see on the internet so that means it couldn't be CBI, to give her that heads up. That might support the ability to do what you're talking about.

MR. FREESE: Okay.

MR. HOFFMAN: You mentioned there were some fields that were blank. Would you recollect what ones you had seen?

MR. FREESE: I believe Ventria in one case. And I didn't say anything about it because obviously I knew what was going on.

MR. HOFFMAN: And the gene --

MR. FREESE: It might have been the gene. It was out in the media that it was lactoferrin or lysozyme or both and it wasn't up on the web site. And in that case it doesn't matter to me because I know, but it raises the question of in other cases where something should be revealed and it isn't, and I just am not aware.

MR. HOFFMAN: I know there have been at least one case that I'm aware of where we didn't have fields filled in. It was one of those large permits and it was just a matter of time getting to it because someone has to put all that information into our database and it wasn't done immediately, but it was eventually done. So those are phenotype fields that had been left out.

So I was just curious, it should say CBI, and if it doesn't that's something we should look into to make sure we do a little better job getting fields properly filled in with CBI or -- They shouldn't be left blank. That's a good suggestion.

MR. FREESE: Another question. I'm wondering if you ever consider doing, or you ever do environmental assessment on non-permit field trials, on notification field trials? It just strikes me if the field trial's particularly large that could perhaps raise some concerns that even for a notification trial where the trait is supposedly less -- where perhaps just the size or some other characteristic might justify an environmental assessment.

Also whether you have a policy on that. I guess I've already asked about the criteria, but I was

thinking more pharmaceutical field trials, but I guess it would also be interesting to know on the notification side too.

MR. TURNER: We're thinking about that as to how size might fit into the whole system. That's about all we can say at this point.

MR. FREESE: It's kind of hard to -- I've noticed some permits become very large, over several thousand acres, but you're never quite sure how that's divided up among the different states. So it could be really huge chunks of land in which case there might be concerns about gene flow where you wouldn't have it with a smaller field trial.

Is there any chance for a state by state breakdown of acreage for the multi-state permits?

MR. HOFFMAN: We have a new database that we're about to implement this fall. That new database will allow us to track information that we're currently not tracking. One of our intentions is to have different kinds of reports that we could be putting up on our web site, just that kind of information. State by state and crop by crop, crop by state kinds of compilations.

Currently we do not track that electronically so

we can't do it, but I think starting in the next few weeks we're going to implement the system, and there may be a few bugs at first, but eventually I think we will be able to do that.

MR. FREESE: So you'll have things like crop by -- - Will this be more along the lines of the pie charts that you have up now, or kind of that level of --

MR. HOFFMAN: Whether we do it as a pie chart or a table, a graph, I'm not sure how we would do that.

MS. SMITH: We're open to suggestions if you have something in mind.

MR. FREESE: This might be more, you might consider it too much work, but even permit by permit it might be interesting to know. Like what the --

MR. HOFFMAN: That gets into a situation where we might be revealing CBI. What we could be doing is a compilation of all the corn in, all the crops in a various state, the actual acreage planted in various crops on a state by state basis. That's something I could see us doing.

I don't see us doing permit by permit breakdowns.

MR. FREESE: I'm just curious as to why if the overall acreage isn't CBI, why a breakdown wouldn't be --

MR. HOFFMAN: Well if -- That often is CBI. But if you compile acreage from many permits then you're not really revealing who's doing what in a specific state.

MS. SMITH: That is what is CBI often is the size of a given field test. That can give away how close the product is to commercialization. So that's why we can bundle them all up and provide that information, because you don't know the size of this company's product as opposed to this one over here.

MR. FREESE: That assumes there's only one field test per states.

MS. SMITH: That depends on what you're looking at. If you have suggestions for what you want us to --

MR. FREESE: I'll think about that a little more. I haven't thought it through really carefully from that perspective. I'm aware that the larger the trial the closer to commercialization.

MR. HOFFMAN: And we would need to be careful because if there's only one field trial in Rhode Island and that was declared as CBI, technically we'd be liable for releasing that information. So we need to be careful that we're not violating something if we

do this. We have to see how it would work out.

MR. NESBITT: I want to interrupt and just point out we have about three minutes left in our allotted 45 minutes, so if you had any sort of closing remarks you'd like to make.

MR. FREESE: Okay.

This kind of gets away from -- You're probably not going to be able to tell me this but I noticed in the database there's been a trend in recent years away from using food crops for pharmaceutical production. I can't recall, I'm trying to remember if you guys, someone told me once that maybe there was some sort of guidance to industry saying we can't say no to anything, but non-food crops are better than food crops for this application. I don't know if you have any sort of policy like that. I just have noticed this trend that I'm just wondering if it's more just a reaction of the companies to what's going on out in the world or if maybe USDA has something going on there.

MS. SMITH: It's probably a mix of reaction to what's happening in the world as well as the difference in questions we may be asking, the information we may be asking depending on what kind

of a crop they're growing it in, so it's probably a little of both.

MR. FREESE: I see. If you ask for more information that might kind of discourage interest to go in a certain direction --

MS. SMITH: We certainly have more questions that we want to be able to answer.

MR. FREESE: I guess the final question, a lot of the EIS seems to be moving in a good direction but I notice there's a lot of talk in -- There's been a debate recently I've seen in the scientific literature, some people are kind of pushing for an end to specific kind of regulation of different transformation events of the same transgenic line. I'm wondering if there's any thought in APHIS of following those kind of recommendations or if you're still going to insist on separate deregulation for different transformation events.

Well, that's a question. Do you sometimes deregulate more than one transformation event? I guess you do in certain cases, don't you?

MR. TURNER: They can ask for deregulation of several events in their petition, and then we can extend the deregulation to other events. That process

is somewhat open in our current regulations as to how that would be done. Right now it's application driven. The dataset.

MR. NESBITT: Unfortunately we are reaching the end of our allotted time for this meeting so, Cindy would you like to have the last word?

MS. SMITH: Actually, I'll let Bill have the last word. I'd just say we appreciate you coming in and acknowledge the limitations we're under but still appreciate your time despite that. This is all good food for the mill.

MR. FREESE: Thanks for having me here.

On a couple of the questions, like the criteria for doing the EA, should I get back to someone or will someone get back to me after maybe you've maybe checked with your lawyers, or how --

MS. SMITH: Here's my suggestion. Questions you want to get a little bit more information from us, something else we can tell you?

MR. FREESE: Uh huh.

MS. SMITH: Do you want to send Clint maybe what those questions are.

MR. NESBITT: Sure, actually even Rebecca does that.

MS. SMITH: Okay. Rebecca. What those questions are and then we can --

MR. FREESE: I think you e-mailed me once. Or do you have a card?

MS. STANKIEWICZ GABEL: I didn't bring it with me. I'll send you another follow-up e-mail.

MR. FREESE: Okay.

MR. NESBITT: Very good, thank you for coming.

MR. FREESE: Thanks for having me.

(Whereupon, at 3:02 p.m., the meeting in the above-entitled matter was adjourned.)

//

REPORTER'S CERTIFICATE

DOCKET NO.: N/A

CASE TITLE: Deputy Administrator Stakeholder Meeting

HEARING DATE: September 22, 2005

LOCATION: Riverdale, Maryland

I hereby certify that the proceedings and evidence are contained fully and accurately on the tapes and notes reported by me at the hearing in the above case before the United States Department of Agriculture.

Date: September 22, 2005

Edwin Wesley
Official Reporter
Heritage Reporting Corporation
Suite 600
1220 L Street, N.W.
Washington, D.C. 20005-4018